



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/678,403	10/03/2003	Paul J. Hindrichs	STJUDE 3.0-009	1004
530 7590 05/25/2010 LERNER, DAVID, LITTENBERG, KRUMHOLZ & MENTLIK 600 SOUTH AVENUE WEST WESTFIELD, NJ 07090				
EXAMINER SZPIRA, JULIE ANN				
ART UNIT		PAPER NUMBER		
3731				
MAIL DATE		DELIVERY MODE		
05/25/2010		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/678,403

Applicant(s)

HINDRICHs ET AL.

Examiner

JULIE A. SZPIRA

Art Unit

3731

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 December 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 17, 18, 20, 23-31, 33, 36, 54 and 56-67 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 17, 18, 20, 23-31, 33, 36, 54 and 56-67 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Receipt is acknowledged of applicant's amendment filed 12/4/2009. Claims 17, 18, 20, 23-31, 33, 36, 54 and 56-67 are pending and an action on the merits is as follows.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. Claims **17, 18, 22, 24-31, 54, 66 and 67** are rejected under 35 U.S.C. 103(a) as being obvious over **Vargas et al. (US 6,371,964)** in view of **Swanson et al. (US 6,113,612)**.

Regarding claims 17 and 66, Vargas et al. discloses a connector for use in making a hollow anastomotic connection between a first aperture in a side wall defined by first and second ends of a tubular graft tissue conduit having interior and exterior surfaces and a second aperture in a side wall defined by first and second ends of a

tubular body tissue conduit having interior and exterior surfaces in a patient, the connector comprising: a structure capable of being configured to make the hollow anasomotic connection between the first aperture in the sidewall of the tissue conduit and the second aperture in the sidewall of the tubular body conduit that is substantially annularly continuous but annularly enlargeable about its longitudinal axis (figure 1 item 14 lower part of upper portion 18), the structure including: a first portion (24), that includes first and second groups of members where in the first group of members extends away from the structure (figure 1 item 14 , upper part of upper portion 18), wherein a distal perimeter is defined by at least the first group of members, the first group of members is capable of being configured to penetrate through the exterior surface of the tissue conduit and the interior surface of the graft tissue conduit about the first aperture and to engage the interior surface of the body tissue conduit about the second aperture, and the second group of members (figure 1 lower portion 16) is configured to engage the exterior surface of the graft tissue conduit about the first aperture; and a second portion (any portion proximal to the first group of first members so that there is space between the two portions, "portion" is broad such that it is not limiting in any way) proximal to the portion, wherein a first spacing is defined between at least the first group of first members and the second portion, and wherein the structure is configured to expand from a deformed configuration having a collapsed distal perimeter to an expanded configuration having an expanded distal perimeter (Column 3 Line 20) but fails to disclose the first portion and the second portion being joined

together to define a plurality of cells each having a medial portion, each cell being joined to an adjacent cell only at the medial portion.

However Swanson et al. teaches an anasomotic connector that a first portion and a second portion defining a plurality of cells (Figure 13, defined by 460/462/464/466) each having a medial portion (454), and each cell being joined to an adjacent cell only at the medial portion (Figures 12 and 13).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to only join the cells at the medial portion to allow the cells to be able to deflect radially outwardly from the medial connections to ensure a strong connection between the two joined vessels (column 9, line 34-column 10, line 8).

Regarding claim 18, Vargas et al. discloses The connector defined in claim 17, wherein the first and second groups of members are substantially radially aligned with respect to a common axis (figure 1).

Regarding claim 24 and 67, Vargas et al. discloses a connector for use in making a hollow anastomotic connection between a first aperture in a side wall defined by first and second ends of a tubular graft tissue conduit and a second aperture in a side wall defined by first and second ends of a tubular body tissue conduit in a patient, the connector comprising: a hollow structure that is substantially annularly continuous but annularly enlargeable about its longitudinal axis and configured for disposition substantially perpendicular to the longitudinal axis of the tubular graft conduit and the tubular body conduit (24), the structure including: a distal axial portion (Figure 1 item 14 lower part of upper portion 18), wherein a plurality of first members (figure 1 item 14

upper part of upper portion 18) extend away from the distal axial portion in an annular array that is substantially concentric with the structure, wherein a distal perimeter is defined by at least a first group of the plurality of first members configured to engage the interior wall of the body tissue conduit about the second aperture, and wherein a second group of the plurality of first members (figure 1 item 14 lower part of upper portion 18) is configured to engage the graft tissue conduit about the first aperture; a proximal axial portion (figure 1 item 14 upper portion of lower part 16), wherein a proximal perimeter is defined by a plurality of second members of the proximal axial portion (figure 1 item 14 lower part of lower portion 16) configured to engage the exterior wall of the body tissue conduit about the second aperture; and a medial axial portion (24 portion not including "structure") between the distal axial portion and the proximal axial portion, wherein an axial spacing is defined between at least the first group of first members and the plurality of second members, and wherein the structure is configured to expand from a deformed configuration having a collapsed distal perimeter and a first axial spacing to an expanded configuration having an expanded distal perimeter and a second axial spacing but fails to disclose the distal axial portion and the proximal axial portion being joined together to define a plurality of cells each having a medial axial portion, each cell being joined to an adjacent cell only at the medial axial portion and having a conical shape.

However Swanson et al. teaches an anasomotic connector that a first portion and a second portion defining a plurality of cells (Figure 13, defined by 460/462/464/466) each having a medial portion (454), and each cell being joined to an adjacent cell only

at the medial portion (Figures 12 and 13) and the connector having a conical shape (Figure 14).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to only join the cells at the medial portion to allow the cells to be able to deflect radially outwardly from the medial connections to ensure a strong connection between the two joined vessels (column 9, line 34-column 10, line 8).

Regarding claim 25, Vargas et al. discloses the connector defined in claim 24, wherein the medial axial portion is configured to extend in a first direction along the exterior of the graft tissue conduit about the first aperture substantially perpendicular to the longitudinal axis of the graft tissue conduit (functional language, structure not differentiated from the reference).

Regarding claim 26, Vargas et al. discloses the connector defined in claim 24, wherein the distal axial portion is configured to receive tissue of the graft tissue conduit about the first aperture extending up through the hollow interior of the structure in a direction substantially perpendicular to the longitudinal axis of the graft tissue conduit (functional language, structure not differentiated from the reference).

Regarding claim 27, Vargas et al. discloses the connector defined in claim 24, wherein the collapsed distal perimeter is smaller than the perimeter of the second aperture (the second aperture refers to the tissue graft, the tissue graft has not been specifically claimed so this claim does not add any structural limitation, however Column 5 Line 43 through Column 6 Line 6 discloses this concept).

Regarding claim 28, Vargas et al. discloses the connector defined in claim 24, wherein the second axial spacing is smaller than the first axial spacing (figure 2).

Regarding claim 29, Vargas et al. discloses the connector defined in claim 24, wherein at least the first group of first members and the plurality of second members are configured to resiliently press the graft tissue conduit and the body tissue conduit into annular contact with one another annularly around the first and second apertures (functional language, structure not differentiated from reference).

Regarding claim 30, Vargas et al. discloses the connector defined in claim 24, wherein the second axial spacing is substantially equal to the sum of the wall thickness of the graft tissue conduit and the wall thickness of the body tissue conduit (graft tissue and body tissue not specifically part of claimed structure, therefore claim does not include any new limitation, however Column 5 Line 43 through Column 6 Line 6 discloses this concept).

Regarding claim 31, Vargas et al. discloses the connector defined in claim 24, wherein the first and second groups of first members are substantially radially aligned with respect to the longitudinal axis of the structure (figure 1).

Regarding claim 54, Vargas et al. discloses an apparatus for producing a hollow anastomotic connection between a first aperture in a side wall defined by first and second ends of a graft tissue conduit and a second aperture in a side wall defined by first and second ends of a body tissue conduit in a patient, comprising: a connector having a structure that is substantially annularly continuous but annularly enlargeable about its longitudinal axis (24), the structure including: a first portion (figure 1 lower part

14 of upper portion 18), wherein the first portion includes a plurality of first members extending away from the structure (figure 1 upper part of upper portion 18), wherein a distal perimeter is defined by at least a first group of the plurality of first members configured to engage the interior wall of the body tissue conduit about the second aperture, and wherein a second group (figure 1 upper part 14 of lower portion) of the plurality of first members is configured to engage the graft tissue conduit about the first aperture; and a second portion (any portion proximal to the first group of first members so that there is space between the two portions, "portion" is broad such that it is not limiting in any way) proximal to the first group of first members, wherein a first spacing is defined between at least the first group of first members and the second portion, and wherein the structure is configured to expand from a deformed configuration having a collapsed distal perimeter to an expanded configuration having an expanded distal perimeter (Col 3 Line 20); and a delivery tool (Figures 4-6) having a first configuration and a second configuration, wherein the first configuration is configured for retaining a retainable portion of the connector proximal to the first group of first members to deform the connector structure from the expanded configuration to the deformed configuration and to advance the collapsed distal perimeter of the connector into the lumen the body tissue conduit via the second aperture, and wherein the second configuration is configured for releasing the retainable portion of the connector to reform the connector structure from the deformed configuration to the expanded configuration but fails to disclose the first portion and the second portion being joined together to define a

plurality of cells each having a medial portion, each cell being joined to an adjacent cell only at the medial portion.

However Swanson et al. teaches an anasomotic connector that a first portion and a second portion defining a plurality of cells (Figure 13, defined by 460/462/464/466) each having a medial portion (454), and each cell being joined to an adjacent cell only at the medial portion (Figures 12 and 13).

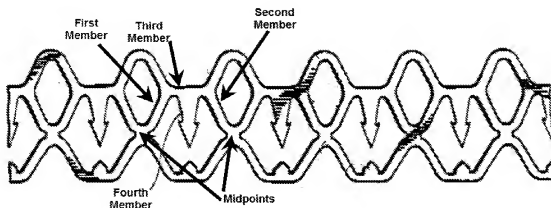
It would have been obvious to one having ordinary skill in the art at the time the invention was made to only join the cells at the medial portion to allow the cells to be able to deflect radially outwardly from the medial connections to ensure a strong connection between the two joined vessels (column 9, line 34-column 10, line 8).

Regarding claims 56 and 57, Vargas discloses the structure of the connector configured for disposition such that the longitudinal axis of the structure is substantially perpendicular to the body conduit, but fails to disclose the axis being substantially perpendicular to the graft conduit.

It would have been obvious to one having ordinary skill at the time to use the tubular graft at an orientation perpendicular to the connector device if the device was being used in a midsection of the graft conduit instead of at the end of the conduit. The claimed orientation of the connector device does not differentiate the device from the structural limitations disclosed in prior art.

4. **Claims 58-61** are rejected under 35 U.S.C. 103(a) as being obvious over **Swanson et al. (US 6,602,263)** in view of **Swanson et al. (US 6,113,612)**.

Regarding claims 58-61, Swanson et al. '263 discloses a connector for use in making a hollow anastomotic connection, the connector comprising: a plurality of hollow cells, wherein the hollow cells are adjoined in an annularly continuous manner, wherein the plurality of hollow cells are annularly enlargeable about a common longitudinal axis, wherein each hollow cell comprises first and second midpoints; a distal portion that includes a top section and a bottom section, wherein: the bottom section includes a first member extending from the first midpoint towards the top section and a second member extending from the second midpoint towards the top section; and the top section includes (1) a third member between the first and second members and (2) a fourth member that extends from the third member in a direction away from the third member and the hollow cell; and a proximal portion joined to the bottom section of the distal portion at the first and second midpoints; wherein a distal perimeter when the hollow cell is in a deformed configuration is defined by the third members of the plurality of hollow cells and a proximal perimeter different from the distal perimeter is defined by end segments of the proximal portions of the plurality of hollow cells (See Figure Below; Figures 4 and 5), and the fourth member extends in a direction normal to the third member (Figure 4) and in a direction between a normal of the third member and a plane of the first cell (Figure 5), with the end segments oriented in a direction parallel to the third member, but fails to disclose the first portion and the second portion being joined together only by a connection between the first midpoint of one cell and the second midpoint of the adjacent cell to define a plurality of cells.



However Swanson et al. '612 teaches an anastomotic connector that has a first portion and the second portion being joined together only by a connection between the first midpoint of one cell and the second midpoint of the adjacent cell (medial portion 454) to define a plurality of cells (Figure 13, defined by 460/462/464/466).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to only join the cells at the midpoint (medial portion) to allow the cells to be able to deflect radially outwardly from the medial connections to ensure a strong connection between the two joined vessels (column 9, line 34-column 10, line 8).

5. **Claims 20, 23, 33 and 36** are rejected under 35 U.S.C. 103(a) as being unpatentable over **Vargas (US 6,371,964)** in view of **Swanson et al. (US 6,113,612)** further in view of **Lazarus (US 5,397,345)**.

Vargas et al. in view of Swanson et al. discloses the invention substantially as claimed as stated above. Vargas does not explicitly disclose hooks or barbs on the first members. Lazarus teaches the use of hooks and barbs to engage the tissue or graft wall (Item 70). Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify Vargas' members to include

Lazarus' barbs and hooks. Such a modification would engage the graft material so the vessels remain connected.

6. **Claims 62-65** are rejected under 35 U.S.C. 103(a) as being unpatentable over **Vargas (US 6,371,964** in view of **Swanson et al. (US 6,113,612)** further in view of **Swanson et al. (US 6,602,263)**.

Vargas in view of Swanson et al. '612 discloses the invention substantially as claimed above, but fails to disclose when the structure is in the deformed configuration or expanded configuration, the distal perimeter is different that the maximum proximal perimeter.

However, Swanson et al. '263 teaches the distal and proximal perimeters being different (Figure 5, elements 242 and 240).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have different diameters in the distal and proximal regions to allow for the device to decrease axial spacing of the device to allow for a better approximation of the joined conduits (column 9, lines 1-19).

Response to Arguments

7. Applicant's arguments filed 12/4/2009 have been fully considered but they moot in view of the new ground(s) of rejection.

Conclusion

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JULIE A. SZPIRA whose telephone number is (571) 270-3866. The examiner can normally be reached on Monday-Thursday 9 AM to 6 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anh Tuan Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J. A. S./
Examiner, Art Unit 3731
May 19, 2010

/TODD E. MANAHAN/
Supervisory Patent Examiner, Art Unit 3734